

**10/575615**

**IAP20 Rec'd PCT/PTO 12 APR 2006**

## APPENDIX D



# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>IMG/44825PCT</b>	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. <b>PCT/GB2004/004416</b>	International filing date (day/month/year) <b>18.10.2004</b>	Priority date (day/month/year) <b>17.10.2003</b>	
International Patent Classification (IPC) or national classification and IPC <b>A61M15/00</b>			
Applicant <b>VECTURA LIMITED et al.</b>			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 2 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  <b>13.05.2005</b>		Date of completion of this report  <b>24.11.2005</b>	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  <b>Borowski, A</b> Telephone No. +49 89 2399-2758 	

10/575615

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/004416

**IAP20 Rec'd PCT/PTO 12 APR 2006**

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3 and 23.1(b))
    - ☐ publication of the international application (under Rule 12.4)
    - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-40 as originally filed

**Claims, Numbers**

8-70 as originally filed  
1-7 received on 17.05.2005 with letter of 13.05.2005

**Drawings, Sheets**

1/21-21/21 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):
  4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/004416

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 32-35

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 32-35

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/004416

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**Box No. IV Lack of unity of invention**

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1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☒ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
  - ☐ the parts relating to claims Nos. .

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-31, 36-70
	No: Claims	
Inventive step (IS)	Yes: Claims	1-31,36-70
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-31,36-70
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/004416

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/GB2004/004416

**Re Item III****Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Rule 67(iv) PCT: Claims 32-35 relate to a method for treatment of the human or animal body by therapy: a method of using an inhaler. The method includes inhaling through the mouthpiece to entrain a dose of medicament and carry it to the user's airway. For said claims no international search report has been established and, consequently, no examination has been carried out with respect to the novelty, inventive step and industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item IV****Lack of unity of invention**

This International Preliminary Examination Authority considers that there are the following 2 inventions claimed in the international application:

- a) the subject-matter of independent claim 1, followed by dependent claims 2 to 31 and 64-70,
- b) the subject matter of independent claim 36, followed by dependent claims 37 to 63.

These 2 inventions are not so linked that they form a single general inventive concept (Rule 13.2 PCT). The single general inventive concept linking the inventions according to different claims can be defined by the common features of these claims. In the present case these common features are at the most an inhaler, comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, and a blister piercing means (a member in claim 1 and a head in claim 36) for puncturing the lid of a blister so that the dose contained in the blister can be subsequently inhaled by the user.

An inhaler according to these features, however, is known from the document WO01/26720 (see for example figures 11-14).

Consequently, the single general concept in the present case is not novel (and hence non

inventive) and the application, therefore, does not comply with the requirements of unity of invention (Rule 13.1 PCT).

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

1. Reference is made to the following documents :

D1: GB-A-2 340 758 (BESPAK PLC) 1 March 2000 (2000-03-01)

D2: WO 99/47099 A (SCHUCKMANN ALFRED VON ; HETZER ULRICH (DE);  
KUBLIK HEIKE (DE); HECKENM) 23 September 1999 (1999-09-23)

D3: WO 90/13328 A (RIKER LABORATORIES INC) 15 November 1990 (1990-11-  
15)

D4: FR2701653 (VALOIS) 26 August 1994(1994-08-26)

Document D4 was not cited in the international search report. A copy of the document is appended hereto.

1. **First invention**

1.1 The subject-matter of independent claim 1 appears to be new (Article 33(2) PCT) and inventive (Article 33(3) PCT).

Document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows an inhaler (1) comprising a housing (4) to receive a plurality of blisters (11) each having a puncturable lid (22) and containing a dose of medicament (21) for inhalation by a user, an actuator (2, 50, 51, 52) operable to sequentially move each blister into alignment with a blister piercing member (30), said actuator being operable to cause the blister piercing member to puncture the lid of an aligned blister such, that, when a user inhales through a mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user's airway (page 11, lines 2-16).

The subject-matter of claim 1 differs from this known inhaler in that:

- the housing is adapted to receive a coiled strip of blisters;



- the actuator is pivotally mounted to the housing operable to cause the coiled strip of blisters to unwind;
- the actuator comprises the mouthpiece and is adapted to pivot with the mouthpiece.

The problem to be solved by the present invention may be regarded as how to provide a device having simpler construction.

A combination of documents D1, D3 and D4 (wherein D3 discloses an inhaler comprising coiled strip of blisters and D4 discloses an inhalator having a pivoting mouthpiece playing the role of an actuator) cannot be considered as obvious to those skilled in the art - especially there is no hint in D4 (inhaler having a powder container and means for providing single doses of powder) to combine the feature of a pivotal mouthpiece/actuator with an inhaler of D1.

- 1.2 Claims 2-31 and 64-70 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

## **2. Second invention**

- 2.1 The subject-matter of independent claim 36 appears to be new (Article 33(2) PCT) and inventive (Article 33(3) PCT).

Document D2 is regarded as being the closest prior art to the subject-matter of claim 36, and shows an inhaler comprising a housing to receive one or more blisters (11, 12) having a puncturable lid (26, 27) and containing a dose of medicament (21, 22) for inhalation by a user, the device comprising a blister piercing head (64) for puncturing the lid of a blister so that the dose contained therein can be inhaled by the user from the blister through the device, wherein the piercing head comprises a primary cutting element (127) which is configured to cut, as the piercing member enters the blister, a first linear slit in the lid and, secondary cutting elements (129, 131), which are configured to cut second linear slits, as the piercing head continues to enter the blister (fig. 12(a)-14(b)).

The subject-matter of claim 36 differs from this known inhaler in that the secondary

cutting elements extend laterally from the primary cutting element and the second linear slits extend across each end of the first linear slit, and the primary and secondary cutting elements form together a pair of flaps in the lid which are folded aside by the piercing head upon further entry of the piercing head into the blister.

The problem to be solved by the present invention may be regarded as how to improve the efficiency of emptying a blister during application (inhalation) on a simple way (with a simple construction of the puncturing head).

All documents cited in the search report do not mention or even suggest such construction of the head.

- 2.2 Claims 37-63 are dependent on claim 36 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**Re Item VII**

**Certain defects in the international application**

1. Independent claims 1 and 36 have not been drafted in the two-part form, as normally required by Rule 6.3(b) PCT.
2. The features of the claims have not been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. All dependent claims referring back to several previous claims should have been grouped together to the extent and in the most practical way possible (Rule 6.4(c) PCT), which is not the case for claims 64-70.

**Re Item VIII**

**Certain observations on the international application**

Some of the features in the apparatus claim 1 relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features: "*a mouthpiece through which a dose of medicament is inhaled by a user*". The intended limitations are

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

**PCT/GB2004/004416**

therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

## Claims

1. An inhaler comprising a housing to receive a coiled strip of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, an actuator pivotally mounted to the housing operable to cause the coiled strip of blisters to unwind so as to sequentially move each blister into alignment with a blister piercing member, said actuator also being operable to cause the blister piercing member to puncture the lid of an aligned blister, the actuator further comprising a mouthpiece through which a dose of medicament is inhaled by a user, the inhaler being configured such that, when a user pivots the actuator or causes it to pivot, together with the mouthpiece, relative to the housing and then subsequently inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user's airway.
2. An inhaler according to claim 1, wherein the actuator is pivotally mounted to the housing.
3. An inhaler according to claim 1 or claim 2, wherein the actuator comprises an arm pivotally mounted to the housing at one end.
4. An inhaler according to claim 3, wherein the blister piercing member depends from one side of said arm positioned so as to extend through an aperture in the housing in a closed position, in which the arm lies substantially against the housing, to pierce the lid of a blister aligned with the blister piercing member.
5. An inhaler according to claim 3 or 4, wherein the piercing member comprises at least two discrete piercing heads operable to pierce a corresponding number of holes in a blister aligned with the blister piercing member.
6. An inhaler according to claim 5, wherein each piercing head comprises a primary cutting element and a pair of secondary cutting elements extending laterally across each end of the primary cutting element.

- 41a -

7. An inhaler according to claim 6, wherein the primary cutting element and the secondary cutting elements each have a pointed tip, the tip of the primary cutting element extending beyond the tips of each of the secondary cutting elements.